AMENDMENTS TO THE CLAIMS

This listing of claims replaces all previous versions and Listings of Claims in the present application

Listing of Claims

Claims 1-42 (cancelled)

43. (withdrawn) A method for administering an exendin or an exendin agonist to a subject in need thereof, comprising injecting said subject with about 0.1 to about 0.5 μg per kilogram of an exendin or an exendin agonist.

44. (withdrawn) The method according to claim 43 wherein said injection is administered to said subject from one to three times per day.

45. (withdrawn) The method according to claim 44 wherein said injection is administered to said subject two times per day.

46. (withdrawn) A method for administering an exendin or an exendin agonist to a subject in need thereof, comprising orally administering to said subject about 500 to about 12,000 μg per day of said exendin or exendin agonist in single or divided doses.

47. (withdrawn) The method according to claim 46 wherein from about 500 to about 5,000 μg per day of said exendin or exendin agonist is orally administered.

48. (withdrawn) A method for administering an exendin or an exendin agonist to a subject in need thereof, comprising administering about 100 to about 12,000 μg per day of said exendin or exendin agonist to the pulmonary system of said subject in single or divided doses.

49. (withdrawn) The method according to claim 48 wherein from about 500 to about 1,000 μg per day of said exendin or exendin agonist is administered to the pulmonary system of said subject in single or divided doses.

50. (withdrawn) A method for administering an exendin or an exendin agonist to a subject in need thereof, comprising nasally administering from about 10-1000 to about 1200-12,000 μg per day of said exendin or exendin agonist to said subject in single or divided doses.

51. (withdrawn) The method according to claim 50 wherein from about 10 to about 1,200 μg per day of said exendin or exendin agonist is nasally administered.

52. (withdrawn) A method for administering an exendin or an exendin agonist to a subject in need thereof, comprising the buccal administration of from about 10-1000 to about 1200-12,000 μg per day of said exendin or exendin agonist to said subject in single or divided doses.

53. (withdrawn) The method according to claim 52 wherein from about 10 to about 1,200 μg per day of said exendin or exendin agonist is administered.

54. (withdrawn) A method for administering an exendin or an exendin agonist to a subject in need thereof, comprising the sublingual administration of from about 10-1000 to about 1200-8,000 μg per day of said exendin or exendin agonist to said subject in single or divided doses.

55. (withdrawn) The method according to claim 54 wherein from about 10 to about 1,200 μg per day of said exendin or exendin agonist is administered.

56. (withdrawn) A method for administering an exendin or an exendin agonist to a subject in need thereof, comprising injecting said subject with about 1 μg-30 μg to about 1 mg of an exendin or exendin agonist per day.

57. (withdrawn) The method according to claim 56 wherein said injection is a peripheral injection.

58. (withdrawn) The method according to claim 56 wherein said subject is injected with about 1-30 μg to about 500 μg of said exendin or exendin agonist per day.

59. (withdrawn) The method according to claim 56 wherein said subject is injected with about 1-30 μg to about 50 μg of said exendin or exendin agonist per day.

60. (withdrawn) The method according to claim 56 wherein said subject is injected with about 3 μg to about 50 μg of said exendin or exendin agonist per day.

61. (withdrawn) A method for administering an exendin or an exendin agonist to a subject in need thereof, comprising injecting an exendin or an exendin agonist into said subject in an amount equal to from about 0.005 μg/kg per dose to about 0.2 μg/kg per dose.

62. (withdrawn) The method according to claim 61 wherein said dose is from about 0.02 μg/kg per dose to about 0.1 μg/kg per dose.

63. (withdrawn) The method according to claim 61 wherein said dose is from about 0.05 μg/kg per dose to about 0.1 μg/kg per dose.

64. (withdrawn) The method according to any of claims 61, 62 or 63, wherein said doses are administered to said subject from 1 to 4 times per day.

65. (withdrawn) The method according to any of claims 61, 62 or 63, wherein said doses are administered to said subject from 1 to 2 times per day.

66. (withdrawn) A method for increasing the sensitivity of a a subject to exogenous or endogenous insulin, comprising administering an effective amount of exendin or an exendin agonist to said subject.

67. (withdrawn) The method according to claim 66 wherein said exendin or an exendin agonist is administered by nasal administration.

68. (withdrawn) The method according to claim 66 wherein said exendin or an exendin agonist is administered by oral administration.

69. (withdrawn) The method according to claim 66 wherein said exendin or an exendin agonist is administered by pulmonary administration.

70. (withdrawn) The method according to claim 66 wherein said exendin or an exendin agonist is administered by buccal administration.

71. (withdrawn) The method according to claim 66 wherein said exendin or an exendin agonist is administered by sublingual administration.

72. (withdrawn) The method according to claim 66 wherein said exendin or an exendin agonist is administered by intra-tracheal administration.

73. (withdrawn) The method according to claim 66 wherein said exendin or an exendin agonist is administered by injection.

74. (withdrawn) The method according to claim 73 wherein said injection is a subcutaneous injection.

75. (withdrawn) The method of claim 61 wherein from about 0.01 μg/kg to about 0.2 μg/kg of exendin or exendin agonist is injected.

76. (withdrawn) A method for administering an exendin or an exendin agonist to a subject in need thereof, comprising administering to said subject by injection at least about 0.1 μg/kg of said exendin or exendin agonist per day in single or divided doses.

77. (withdrawn) A method ofr administering an exendin or an exendin agonist to a subject in need thereof, comprising administering to said subject by injection at least about 0.2 μg/kg of said exendin or exendin agonist per day in single or divided doses.

78. (withdrawn) A method for administering an exendin or an exendin agonist to a subject in need thereof, comprising administering to said subject by injection at least about 0.5 μg/kg of said exendin or exendin agonist per day in single or divided doses.

79. (withdrawn) A method for administering an exednin or an exendin agonist to a subject in need thereof, comprising orally administering to said subject at least about 17.5 μg per day of said exending or exendin agonist in single or divided doses.

80. (withdrawn) A method for administering an exendin or an exendin agonist to a subject in need thereof, comprising administering at least about 3.5 μg per day of said exendin or exendin agonist to the pulmonary system of said subject in single or divided doses.

81. (withdrawn) A method of administering an exendin or an exendin agonist to a subject in need thereof, comprising nasally administering at least about 3.5 μg per day of said exendin or exendin agonist to said subject in single or divided doses.

82. (withdrawn) A method for administering an exendin or an exendin agonist to a subject in need thereof, comprising the buccal administration of at least about 3.5 μg per day of said exendin or exendin agonist to said subject in single or divided doses.

83 (withdrawn) A method for administering an exendin or an exendin agonist to a subject in need thereof, comprising the sublingual administration of at least about 3.5 μg per day of said exending or exending agonist to said subject in single or divided doses.

84. (currently amended) A pharmaceutical formulation which is a liquid dosage form suitable for multi-use administration comprising about 0.005% to about 0.4% (w/v) of exendin-4, a buffer, an iso-osmolality modifier, and about 0.005% to about 1.0% ~~w/v~~ (w/v) of a preservative selected from the group consisting of m-cresol, phenol, alcohol, methyl-, ethyl-, propyl- and butyl-paraben and any combination thereof, wherein said formulation has a pH of between about 3.0 and about 7.0.

85. (previously presented) The formulation of claim 84, said formulation having a pH of between about 4.0 and about 6.0.

86. (currently amended) The formulation of claim 84, wherein said exendin-4 is present at a concentration of between about 0.005% ~~to~~ and about 0.05% (w/v).

87. (previously presented) The formulation of claim 84, wherein said buffer is selected from the group consisting of an acetate buffer, a glutamate buffer, a citrate buffer, a phosphate buffer, and any combination thereof.

88. (previously presented) The formulation of claim 84, wherein said buffer comprises an acetate buffer.

89. (previously presented) The formulation of claim 84, wherein said buffer comprises a glutamate buffer.

90. (previously presented) The formulation of claim 84, wherein said buffer comprises a citrate buffer.

91. (previously presented) The formulation of claim 84, wherein said buffer is at a concentration between about 0.02% and about 0.5% (w/v).

92. (previously presented) The formulation of claim 84, wherein said pH is between about 4.0 and about 5.0.

93. (previously presented) The formulation of claim 84, wherein said iso-osmolality modifier is a carbohydrate, a polyhydric alcohol, or a combination thereof, and said iso-osmolality modifier is at a concentration between about 1% and 10% (w/v).

94. (previously presented) The formulation of claim 93, wherein said polyhydric alcohol is selected from the group consisting of sorbitol, mannitol, inositol, glycerol, xylitol, polyethylene glycols, and any combination thereof.

95. (previously presented) The formulation of claim 93, wherein said carbohydrate is selected from the group consisting of galactose, arabinose, lactose, and any combination thereof.

96. (previously presented) The formulation of claim 84, wherein said iso-osmolality modifier is mannitol, sorbitol, or a combination thereof.

97. (previously presented) The formulation of claim 84, wherein said iso-osmolality modifier comprises mannitol.

98. (previously presented) The formulation of claim 84, wherein said iso-osmolality modifier comprises sorbitol.

99. (previously presented) The formulation of claim 84, wherein said preservative comprises m-cresol.

100. (previously presented) The formulation of claim 84, wherein said preservative comprises phenol.

101. (previously presented) The formulation of claim 84, wherein said formulation is suitable for administration via injection to achieve a dose of from about 0.1 μg/kg to about 0.5 μg/kg of said exendin-4.

102. (previously presented) The formulation of claim 84, wherein said formulation is suitable for administration via injection to achieve a dose of from about 0.005 μg/kg to about 0.2 μg/kg of said exendin-4.

103. (previously presented) The formulation of claim 84, wherein said formulation is suitable for administration via injection to achieve a dose of from about 1 μg/day to about 1 mg/day of said exendin-4.

104. (previously presented) A pharmaceutical formulation which is a liquid dosage form suitable for multi-use administration comprising 0.025% (w/v) of exendin-4, 0.159% (w/v) of an acetate buffer, 4.3% (w/v) mannitol, and 0.22% (w/v) m-cresol, wherein said formulation has a pH of 4.5.

105. (currently amended) A pharmaceutical formulation which is a liquid dosage form suitable for multi-use administration comprising exendin-4, a buffer, an iso-osmolality modifier, and about 0.005% to about 1.0% ~~w/v~~ (w/v)of a preservative selected from the group consisting of m-cresol, phenol, alcohol, methyl-, ethyl-, propyl- and butyl-paraben and any combination thereof, wherein said formulation has a pH of between about 3.0 and about 6.0.

106. (previously presented) The formulation of claim 105, wherein said formulation is suitable for oral administration to achieve a dose of from about 500 μg/day to about 12,000 μg/day of said exendin-4 in a single or divided dose.

107. (previously presented) The formulation of claim 105, wherein said formulation is suitable for pulmonary administration to achieve a dose from about 100 μg/day to about 12,000 μg/day of said exendin-4 in a single or divided dose.

108. (previously presented) The formulation of claim 105, wherein said formulation is suitable for nasal administration to achieve a dose from about 10 μg/day to about 12,000 μg/day of said exendin-4 in a single or divided dose.

109. (previously presented) The formulation of claim 105, wherein said formulation is suitable for buccal administration to achieve a dose from about 100 μg/day to about 12,000 μg/day of said exendin-4 in a single or divided dose.

110. (previously presented) The formulation of claim 105, wherein said formulation is suitable for sublingual administration to achieve a dose from about 10 μg/day to about 8,000 μg/day of said exendin-4 in a single or divided dose.

111. (previously presented) The formulation of claim 105, said formulation having a pH of between about 4.0 and about 6.0.

112. (previously presented) The formulation of claim 105, wherein said pH is between about 4.0 and about 5.0.

113. (previously presented) The formulation of claim 105, wherein said buffer is selected from the group consisting of an acetate buffer, a glutamate buffer, a citrate buffer, a phosphate buffer, and any combination thereof.

114. (previously presented) The formulation of claim 105, wherein said buffer comprises an acetate buffer.

115. (previously presented) The formulation of claim 105, wherein said buffer comprises a glutamate buffer.

116. (previously presented) The formulation of claim 105, wherein said buffer comprises a citrate buffer.

117. (previously presented) The formulation of claim 105, wherein said buffer is at a concentration between about 0.02% and about 0.5% (w/v).

118. (previously presented) The formulation of claim 105, wherein said iso-osmolality modifier is a carbohydrate, a polyhydric alcohol, or a combination thereof, and said iso-osmolality modifier is at a concentration between about 1% and 10% (w/v).

119. (previously presented) The formulation of claim 118, wherein said polyhydric alcohol is selected from the group consisting of sorbitol, mannitol, inositol, glycerol, xylitol, polyethylene glycols, and any combination thereof.

120. (previously presented) The formulation of claim 118, wherein said carbohydrate is selected from the group consisting of galactose, arabinose, lactose, and any combination thereof.

121. (previously presented) The formulation of claim 105, wherein said iso-osmolality modifier is mannitol, sorbitol, or a combination thereof.

122. (previously presented) The formulation of claim 105, wherein said iso-osmolality modifier comprises mannitol.

123. (previously presented) The formulation of claim 105, wherein said iso-osmolality modifier comprises sorbitol.

124. (previously presented) The formulation of claim 105, wherein said preservative comprises m-cresol.

125. (previously presented) The formulation of claim 105, wherein said preservative comprises phenol.

INTERVIEW SUMMARY

Applicant wished to thank the Examiner for the telephonic interview conducted with the Applicant's representative, James E. Butler, on September 9, 2004. In that interview the outstanding rejections under 35 U.S.C. 112, second paragraph were discussed. During the interview it was agreed that the outstanding rejections under 35 U.S.C. 112, second paragraph would be withdrawn. Applicant agreed to submit a response setting forth the arguments for withdrawal of the rejections.